mayo

Mayo Clinic
200 First Street SW
Rochester, Minnesota 55905
507-284-2511

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J. W. Yunginger, M.D.
Allergic Diseases Research

August 3, 1998

Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20857

Re: Docket No. 98N-0339

Dear Sir or Madam:

I would like to comment on the approach the FDA should use to ensure that it has continued access to the scientific and technical expertise needed to meet its statutory obligations and strengthen its science-based decision-making process.

I am the outgoing Chair of the FDA Allergenic Products Advisory Committee; my term of office expires August 31, 1998. In my opinion, this committee is not used to full advantage by CBER.

1. During my four-year period of service, committee meetings were frequently canceled, and when meetings were held, the agenda was tightly controlled by the committee administrator. Committee members were reminded that their collective opinions were sought only about the agenda items listed.

2. There was no attempt to provide follow-up information about items discussed at previous meetings of the committee; provision of this information would enable committee members to feel their input and suggestions were actually valued.

3. During committee meetings, emphasis was placed (appropriately) on protecting the proprietary rights of allergen extract manufacturers. However, in my opinion, this need for protection was sometimes cited to discourage or deflect probing questions from committee members.

4. Greater use of the committee members' expertise would not necessarily increase costs to FDA; the committee met quite effectively by video and telephone conference call during the past two years. If the committee continues to meet in this fashion, new committee members could be recruited for their expertise, rather than for their geographic proximity to Washington, DC.

Thank you for the opportunity to comment on these matters.

Sincerely,

John W. Yunginger, M.D.
Allergic Diseases Research Laboratory

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mayo

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200 First Street SW
Rochester, Minnesota 55905

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Rockville, MD 20857

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